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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ROSENBERGER, RICHARD A

ART UNIT	PAPER NUMBER
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2877

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/767,709

Applicant(s)

FLAHERTY ET AL.

Examiner

Richard A. Rosenberger

Art Unit

2877

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/5/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 28-43, 47-62 and 64-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 44-46, 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Applicant's election of Group I, claims 1-27, 44-46, and 63, in the reply filed on 06/05/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The non-elected claims should be cancelled. It is noted that the cancellation of the non-elected claims will in no manner prejudice the filing of those claims or the subject matter therein in a divisional application.

2. Claims 12-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear whether and to what degree claims 12 and 18 claim or are intended to claim the "device that quantifies ..." in the preamble of the claims. The claims present the device in the preamble as intended use ("for use with ..."), and not as claimed subject matter, but claim 12 calls for "means for installing said disposable sensor into the device", and claim 18 claims "interface means for interfacing the sensor with the device", which appears to require that the device be at least broadly claimed, so the claims, as currently worded, do not clearly set forth the scope of the claims. Additionally, at least claims 19, 20, and 21 then add additional subject matter all of which appear to include part of the device as well as the sensor, and thus add to the unclarity.

3. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is unclear in that it is obviously incomplete. Claim 20 calls for “means to align electrical contacts associated with the sensor with appropriate location or locations on said device”, but nowhere claims anything associated with the device that would require, or even that would allow for, electrical connection. It is clear that the claim is incomplete in that the claimed electrical contacts have no claimed purpose, use, or other functional relationship to anything that is otherwise claimed.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-5, and 10-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 36 of copending Application No. 10/334,625. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same subject matter with no more than obvious differences.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 36 of the copending application calls for a sensing element; such as sensing element is disposable. It is claimed as being in a sample chamber, which is a housing, which is also disposable, it can be disposed of. Claim 36 of the copending application claims a light source, a detector, and a signal processor, which is a gas analysis device which is usable with the sensors for measuring the concentration of an analyte. Claim 36 of the copending application claims the sensor element comprises a sol-gel, and claims it also comprises "biological material" which is clearly intended to include within its scope cytochrome-c. Although the claim of the copending application does not specifically claim nitric oxide as the detected analyte, it is clear that the claimed "trace analyte" of the claim is intended to include nitric oxide within its scope. Claim 36 claims "means of controlling the humidity", which is a "means for conditioning the gas" as in instant claim 10. It is clearly obvious to calibrate the system of claim 36 of the copending reference in order to obtain the art-recognized benefits of calibration.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-4, 10-15, 18, 22-25, 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaston et al (US 6,033,368).

As in claims 1, 12 and 18, the reference shows a method and apparatus of measuring the concentration of an analyte in a gas sample of exhaled breath, comprising: providing a first disposable (column 5, lines 2-3) sensor (sample analysis assembly 9), said first sensor comprising a sensing element (the colorimetric reagents, see column 3, line 23), wherein said sensing element undergoes a change in the presence of said analyte; loading said first sensor into a gas analysis device (10) through an interface (column 5, lines 9-13); measuring the concentration of said analyte in an exhaled breath sample using said first disposable sensor and said gas analysis device (column 4, lines 62-67); removing said first sensor from said device; and installing a second disposable sensor into said device (column 5, lines 7-11; clearly when a new disposable unit is attached to analyzer 10, the previously installed disposable unit must be first removed).

As in claims 2 and 13, the reagents of the reference are disposed in a disposable housing. As in claims 3 and 14, the change in the reagent is an optically quantifiable characteristic. As in claim 4 and 15, nitric oxide is being measured.

As in claim 10, the gas is conditioned prior to measurement; see the filter of claim 12, which conditioned the gas by removing the particulates, and the condenser which conditions the gas by condensing out the water vapor.

As in claim 11, the reference teaches that the analyzer 10 “calibrates the absorbance/concentration relationship based on standard samples”; the information concerning these standard samples used for this calibration is “calibration information associated with the sensor”; if the information were not “associated with the sensor”, the calibration would be useless.

As to claim 63, the reference clearly intends, and would be understood by those in the art through any fair reading, of including in its disclosure a plurality of disposable sensors to be used in the non-disposable analyzer (10). The use of words such as disposable and non-disposable can only be reasonably understood as teaching more than one disposable unit to be placed in the analyzer. The gas analyzer (10) and the plurality of disposable sensors for use with the analyzer together comprise a “kit” as in claim 22. As set forth above, the disposable sensors are in a disposable housing as in claims 23, are responsive to the analyte as in claim 24, and the analyte is nitric oxide as in claim 25.

9. Claims 7, 19, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaston et al (US 6,033,368).

See above.

As for claims 7 and 44, Gaston et al does not discuss in detail the arrangement of the actual measuring portion of the analyzer, stating that it is “an association of conventional elements”. It is so well known in the art that official notice can be taken that such optical measurement systems are conventionally placed in housings which perform the function of shielding the sample and detector from ambient light, or, as claims 7 and 44 term it, “extraneous signals”. It would have been obvious to include such a housing in the system of Gaston et al because, as is standard practice and common knowledge in the art, beneficial not to have ambient light interfere with optical measurements.

As for claim 19, Gaston et al discusses the “interface means” “to hold the disposable and non-disposable units together at the appropriate orientation” (column 5, lines 11-13), which clearly includes having the sensor element itself aligned with one or more appropriate locations in the analyzer. While the reference does not appear to specifically teach a window in the disposable unit, it would have been obvious to include such a window in order to seal off the sensor unit from possible contamination or other damage and thus help maintain the accuracy and utility of the sensor unit.

10. Claims 12, 15-17, 18, 19, 22, 24-27, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Aylott et al, “Optical Biosensing of Gaseous Nitric Oxide Using Spin-Coated Sol-Gel Thin Films”, Chemistry of Materials, 1997, 9, 22-61-2263.

The language of claims 12, 18 and 63 that the sensor is for measuring a sample “of exhaled breath” is a non-limiting statement of intended use; there is no structure in the

claims to specifically adapt the claimed structure to that use, nor any other structure to bring that intended use into the scope of the claims.

As in claims 12 and 18, the reference shows in figure 1 a sensing element (the protein doped sol-gel thin film) which is responsive to an analyte (NO). There is a device (the flow-through cell and the light source and detector) which quantifies the concentration of the analyte in a gaseous sample” As the sensor is in fact installed in, and interfaced with, the device in a manner which allows for measurement, there is necessarily means for installing it and for interfacing with it. The sensing element is disposable; it can be disposed of.

As for claims 22 and 63, the reference states that a plurality of films were in fact prepared; note the use of the plural in referring to the film in the second full paragraph of the second column of page 2261. The films were clearly prepared to be installable in the device of figure 1 of the reference.

As in claim 24, the sensor is optically responsive to the analyte. As in claims 15 and 25, the analyte is nitric oxide, as in claim 16 and 26 the sensing element is a sol-gel, and as in claim 17 and 27 the sensing element additionally comprises cytochrome-c.

As in claim 19, there is a window (the optical window in figure 1 of the reference)

11. Claims 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Watson et al (US 5,831,742).

The Watson et al reference shows a sensor (a glass slide coated with the gas sensitive polymer which undergoes a color change, column 3, lines 49-52) within a

housing with means to account for the effect of interfering signals comprising two gas cells (16, 18) with a second sensing element in the housing (column 6, lines 27-39).

12. Claims 1-27, 44-46 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aylott et al, "Optical Biosensing of Gaseous Nitric Oxide Using Spin-Coated Sol-Gel Thin Films", Chemistry of Materials, 1997, 9, 22-61-2263, taken with Gaston et al (US 6,033,368) and Bollinger et al (US 6,635,415), and Watson et al (US 5,831,742).

Aylott et al discusses the known use of a sensor element comprising cytochrome-c in a sol-gel as a sensor element to measure nitric oxide in gas by passing the gas past the sensor element and using optical measuring means to measure the color change of the element due to the nitric oxide. See figure 1 of Aylott et al in particular.

Aylott et al does not specifically mention the use of such a sensor element to measure nitric oxide in breath. It is known in the art to measure nitric oxide in breath; see Gaston et al and Bollinger et al (preamble of claim 1 of the reference). It would have been obvious to measure nitric oxide in breath using the type of sensor element discussed by Aylott et al because it is a known means to make a measurement which is known to be useful.

Aylott et al does not discuss particular construction details of the measuring system, disclosing it only broadly; it would have been obvious to make the system into a more commercially and medically practical system than the laboratory process discussed by Aylott et al. Placing such a color-changing sensor element in a disposable housing is known in the art; as discussed by Gaston et al; which discloses having a

“disposable unit” which houses the sensor element and a analyzer which is not disposable (column 5, lines 2-5). See also Watson et al, which teaches sensing element (a glass slide coated with the gas sensitive polymer which undergoes a color change, column 3, lines 49-52) which are designed to be inserted into an analyzer (column 6, lines 40-42). Placing a sensor element such as shown by Aylott et al in such a known arrangement would have been obvious so it can be quickly and easily replaced as necessary and making the system more medically safe by replacing portions which are especially prone to transferring germs.

As in claims 7-9 and 44-46, Watson et al shows that it is known to provide a second sensor element in a second separate channel for use as a reference (Watson, column 6, lines 27-39). It would have been obvious to use the known technique of its known purpose of improving the measurement accuracy.

As in claim 10, conditioning the gas prior to measurement is taught as being known in the art by Gaston et al; see the filter of claim 12 of that reference. So conditioning the gas prior to measurement would have been obvious in order to obtain the benefits of such conditioning.

As in claim 11, Gaston et al notes that calibration is known; see column 4, line 66; it would have been obvious to so calibrate in order to obtain the increase in accuracy that such calibration provides.

As in claim 19 and 20, it is clearly obvious to provide means to have the sensor element properly aligned for the test; it would have been foolish to do otherwise as if the sensor is not properly aligned the test cannot proceed properly.


As in claim 20, slots configured to receive an element are so well known in the art for inserting various types of elements in to devices that official notice is sufficient.

As in claims 22- 27 and 63, because the analyzer by itself, as, for example, the analyzers of Gaston et al and Watson et al, is useless without the sensor elements, and the sensor elements need to be replaced, it is clearly obvious to provide sensor elements with the device so the device can in fact be used.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard A Rosenberger whose telephone number is (571) 272-2428. The examiner can normally be reached on Monday through Friday during the hours of 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr. can be reached on (571) 272-2800 ext. 77. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R. A. Rosenberger
23 June 2006



Richard A. Rosenberger
Primary Examiner